

CAUSALITY OF ADVERSE DRUG REACTIONS IN HIV-PATIENTS TREATED WITH BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE

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BACKGROUND AND IMPORTANCE

Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) has been positioned as a preference drug in the main guidelines in the treatment of HIV. BIC/FTC/TAF has demonstrated an excellent safety and efficacy profile in pivotal studies.

AIM AND OBJECTIVES

To assess the causality of adverse drug reactions (ADRs) of HIV-patients treated with BIC/FTC/TAF.

MATERIAL AND METHODS

Observational and retrospective study from may 2019 to march 2021 in a general hospital.

Characterization of the population

Cohort 1: patients who changed their antirretroviral treatment due to an ADR.

Cohort 2: patients who maintained their antirretroviral treatment despite some ADR.

Variables analyzed



Age



Sex



ADRs

Naranjo Algorithm

To assess whether there is a causal relationship between an identified untoward clinical event and a drug.



definite



probably

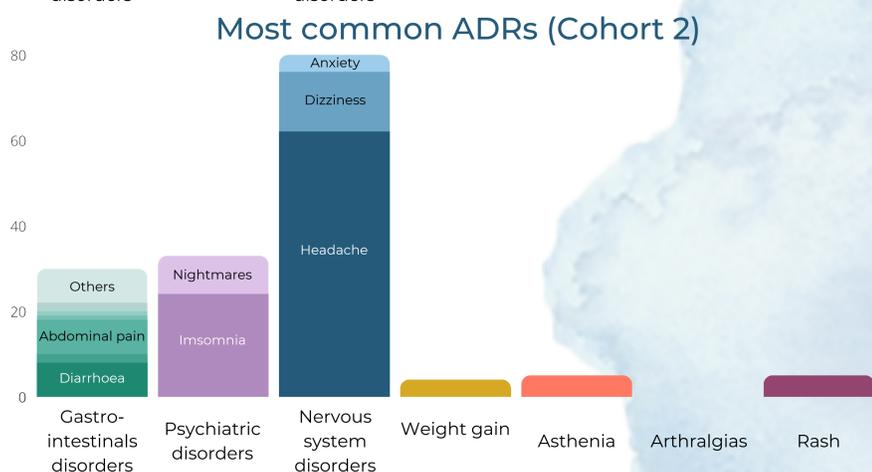
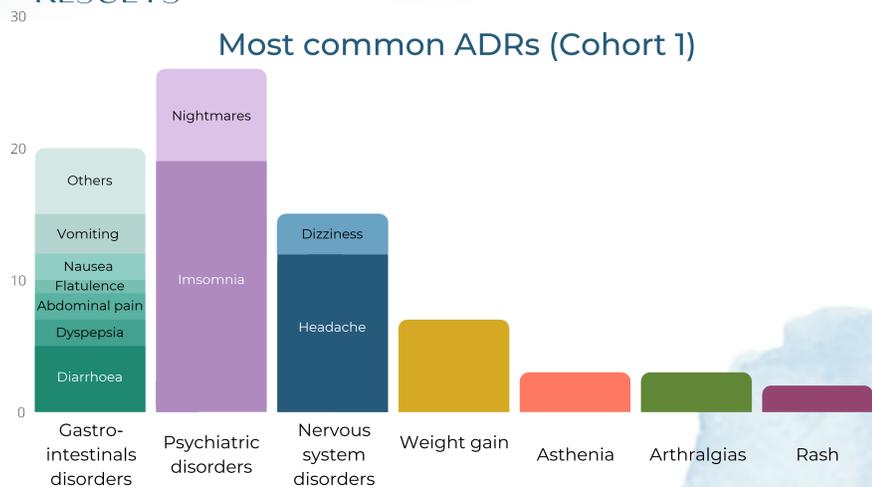


possible



doubtful

RESULTS



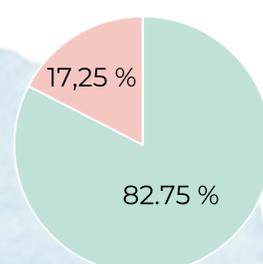
Characterization of the population

N = 1,275 patients

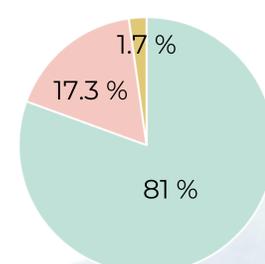
Cohort 1: 27 women vs 25 men and median age 56 [IQR 51 – 60]

Cohort 2: 107 women vs 25 men and median age 45 [IQR 33 – 55]

Causality of ADRs (Cohort 1)



Causality of ADRs (Cohort 2)



Most common ADRs

| | Cohort 1 | Cohort 2 | Total |
|------------------------------|----------|----------|------------|
| Total adverse drug reactions | 87 | 179 | 266 |
| Headache | 12 | 62 | 74 (27.8%) |
| Gastrointestinal disorders | 20 | 30 | 50 (18.8%) |
| Insomnia | 19 | 24 | 43 (16.2%) |

CONCLUSIONS AND RELEVANCE

- The frequency of ADRs of HIV patients in treatment with BIC/FTC/TAF is low and most of people who suffer it can continue with their treatment.
- Most ADRs were consider as probably.
- The most common ADRs was the headaches, the gastrointestinal disorders and the insomnia.

